REMARKS/ARGUMENTS

The Office action mailed on June 17, 2008 has been carefully reviewed and the above identified amendments have been provided to thoroughly address each of the rejections provided by the examiner in that Office action. In addition, the following remarks are submitted to clarify and explain the importance of the above amendments and to support a finding by the examiner that the claims, as amended, are now in a form warranting allowance of this case. Accordingly, the undersigned respectfully requests reconsideration by the examiner in this case.

The examiner had rejected claims 9-11, 16-18 and 20 under 35 U.S.C. §103(a) as being unpatentable over Ahlgren (U.S. Patent No. 6,852,126) in view of Young (U.S. Patent No. 6,190,414); and rejected claim 12 as being unpatentable over Ahlgren in view of Young and in view of Jackson (U.S. Patent No. 6,773,460).

Initially, applicant notes that claim 9 has been amended to clarify which "long axis" is being referred to about which rotation occurs during the last two "rotating" steps of claim 9. Applicant respectfully submits that the examiner has misapplied Ahlgren perhaps due to a misunderstanding as to exactly which axis of rotation is involved. In the case of Ahlgren, any rotation would occur about an axis parallel with or colinear with the spine of the patient. In contrast, the primary and secondary segments of this invention (as now claimed by this amendment) are configured to rotate about a long axis extending between ends of each of the segments. Such axes extend substantially perpendicular to the spine of the patient.

Such rotation in the case of this invention is perhaps best shown in figures 2 and 3 where the primary segment is rotated about axis A (along arrow F), and figures 4 and 5 where the secondary segment is rotated about axis B (along arrow G). Such rotation is completely distinct from rotation taught by Ahlgren. Also, such long axis rotation is frustrated by the faceted contour of the parts taught by Ahlgren. Furthermore, applicant respectfully submits that none of the prior art teach such a form of rotation, such that

even when the teachings of Ahlgren are combined with the teachings of Young, they still do not teach each of the elements of claim 9. With the amendments to claim 9, this axis of rotation for the primary segment and the secondary segment is more clearly set forth.

In addition, applicant has included with this Office action response three declarations according to 37 C.F.R. §1.131 to address rejection of each of the claims in this case under 35 U.S.C. §103(a). These affidavits establish that applicants' invention was completed in this country before the filing date of either the Ahlgren reference (July 17, 2000) or the Jackson reference (December 5, 2000). With such completion of the invention in the United States prior to the filing date of these references cited under §103, applicant respectfully submits that these claims are not made obvious, but rather warrant allowable status.

In particular, the affidavits show both conception and reduction to practice sometime before July 17, 2000. Exhibit A and the declarations establish the fact that inventor Bradley J. Glenn and inventor Gary Schneiderman met and conceived of refinements to the method and apparatus of both this application and the parent application of which this application is a continuation.

Exhibit B and the declaration of Dr. Glenn establish that inventor Brad Glenn on July 14, 2000 purchased materials for construction of prototypes exhibiting the structure and function of this invention according to the invention method claimed herein.

As established by the declaration of Dr. Glenn, the evening of the day that the materials (including styrofoam and balsa wood) were purchased, Dr. Glenn fashioned the styrofoam materials into a first prototype on July 14, 2000 and before the filing date of both the Ahlgren and Jackson references. This first styrofoam prototype was tested by Dr. Glenn at that time and found to be sufficient to show that the invention had the capacity to perform in the manner intended.

Specifically, the testing illustrated that a two element stabilization device could be passed along two separate implantation paths which intersect each other and when such insertion was completed that the two elements would exhibit sufficient interlocking stable support for each other that they could act as a single implant to stabilize vertebrae adjacent an intervertebral space to be effective in stabilizing the spine during a spinal fusion procedure. Dr. Glenn's experience as a surgeon implanting medical devices into patients gave him confidence that the invention was complete and ready for commercialization. The only steps remaining for commercialization and actual use on patients was for the styrofoam prototype to be sized to fit a particular patient and a biocompatible material selected.

Because this first prototype was oversized and commercialization through separate companies was deemed to be more effective with a prototype approximating the size of an implant that would be suitable for implantation into a human spine, the second balsa prototype of Exhibits C, D and E was constructed over two weeks following July 14, 2008. The first styrofoam prototype was not kept as it was considered to be less useful as a marketing tool than the second balsa prototype. Two weeks were required as the balsa material tended to crack when worked and Dr. Glenn desired a refined look since the balsa prototype would be used for marketing the invention to medical device companies.

Applicant acknowledges that the second prototype was not a highly refined and perfected commercial prototype. Rather, the prototypes were fashioned for testing to determine whether the basic method and apparatus of this invention could perform and be performed in the manner intended.

While the degree of testing of an invention required to establish reduction to practice is subject to some imprecision, perhaps the best guidance in this regard is found in the case of *Eastern Rotorcraft Corp. v. United States*, 384 F.2d 429, 431, 155 USPQ 729, 730 (Ct. Cl. 1967). In this case, the court of claims summarized that "the inquiry is

not what kind of test was conducted, but whether the test conducted showed that the invention would work as intended in its contemplated use." Thus, the court of claims focused on the workability of the invention in the context of the problem it solved. The Court of Appeals for the Federal Circuit had similarly suggested that the nature and complexity of the problem necessarily influenced the nature and sufficiency of the testing required to show a reduction to practice (*Scott v. Finney*, 34 F.3d 1058, 32 USPQ 2d 1115, 1119 (Fed. Cir. 1994).

In this case the workability in question was whether or not the independent elements of the device could be manipulated along pathways intersecting each other within an intervertebral space and be positioned crossing each other and with sufficient stability once in their final position to provide the requisite stabilization of the spine. Such testing beneficially was initially conducted by the co-inventor, Dr. Glenn and confirmed two or three days later by the co-inventor Dr. Schneiderman; both of which are trained and licensed surgeons with extensive medical device implantation experience. The inventors could thus manipulate the elements in their hands in a manner simulating a surgical procedure, cause the two elements to intersect each other, rotate the elements appropriately and evaluate the stability of the two elements once joined together. Based on such manipulation, tactile feedback and simultaneous visual inspection, the inventors were able to determine that the device and the method of this invention could be satisfactorily performed in an actual surgical procedure.

No such actual surgical procedure occurred at that time. However, perfection of the invention to the point where it is ready to be put into commercial use is not required to establish a reduction to practice (*Kravig v. Henderson*, 362 F.2d 1015, 150 USPQ 377, 383 (C.C.P.A. 1966). In this case, the test results were sufficient to persuade the inventors to take the risk of commercializing the invention by thereafter presenting the second prototype to a first medical device company Sulzer-Spinetech of Winterthus, Switzerland and setting up this meeting immediately after such testing, culminating in an

exchange of draft non-disclosure agreements on August 20, 2008. A later similar meeting with DePuy Spine, Inc. did result in a commercialization agreement being entered into without further testing or prototype construction being required. Hence, others in addition to the inventors considered the invention to have been sufficiently tested to warrant the risk of commercialization of the invention based on the manufacture and testing of the invention, as embodied in the two prototypes.

In addition to this reduction to practice before the filing date of the Ahlgren and Jackson references, diligence was exhibited from the filing dates of the Ahlgren and Jackson references (July 17, 2000 and December 5, 2000) until further construction and testing of the balsa prototype and until constructive reduction to practice by filing of this patent application on March 27, 2001 of which this application is a continuation. In particular, the inventors spent the second half of the month of July 2000 making the refined balsa prototype for marketing purposes. August 2000 was spent scheduling and preparing for presenting the invention to the Sulzer-Spinetech medical device company. In September or early October 2000 the inventors scheduled a meeting with the registered patent attorney which meeting took place on October 12, 2000. Thereafter, a patentability search was performed and the the inventors promptly hired Mr. Heisler to prepare and file a patent application directed to this invention.

Mr. Heisler proceeded to prepare a draft of the parent of this application over the following three months, including formal drawings and text covering multiple embodiments, with the parent application being prepared in its normal turn according to the workload of Mr. Heisler, as established by the declaration of Mr. Heisler attached. A first draft of the patent application was presented to the inventors which was promptly reviewed by the inventors with appropriate changes made by Mr. Heisler before filing on March 27, 2001. Thus, in addition to the actual reduction to practice described above, the inventors exhibited diligence from the filing dates of the Ahlgren and Jackson references until constructive reduction to practice by filing the patent

application that is the parent of this application.

Accordingly, and for the reasons specified above, applicants submit that they completed this invention before the filing dates of the Ahlgren and Jackson references, such that the rejections under §103 based on these references are overcome. Applicants further note that each of the events described above occurred within the United States of America. Also, the Ahlgren and Jackson references claim elements that are distinct from the claims of this application. For instance, Ahlgren's claims are each limited to a three part construction while the claims of this invention are directed to a method of use of a two part implant. Furthermore, applicant respectfully submits that with the overcoming of this rejection, that the claims in this application, as amended, are now in a form warranting allowable status.

In view of the foregoing, it is respectfully requested that the examiner pass this case to issue. If, upon consideration, the examiner believes further issues remain outstanding or new ones have been generated, the undersigned requests that the examiner call the undersigned to set up a personal or telephone interview with the undersigned to resolve any such remaining issues.

Respectfully Submitted:

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